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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,968

10/24/2003

Alan Smith

25599

6975

23859 7590 05/01/2007
NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

05/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/691,968

Applicant(s)

SMITH ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 41-75, 80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 and 76-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/24/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-40 and 76-79) in the reply filed on 2/5/2007 is acknowledged. The traversal is on the ground(s) that the Examiner has not demonstrated that a serious burden would be required to examine all the claims. This is not found persuasive because the Examiner maintains that a this requirement has already been met by showing that the groups of claims would be classified in different classes. The claims of Group I are directed to a method of delivering a permeant substance (therapeutic substance or drug) through a biological membrane that would be classified in class 604, subclass 500. The Examiner would not have to substantially search in any other class. The claims of Group II include steps for measuring the concentration of substances in the body and comparing the concentrations with known values, which would require a thorough search in class 600. The measuring and concentration steps seem to be computer-controlled which would require a search in multiple other classes such as 700, 717, and 340.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16, 19-36, 39-40, and 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Eppstein (6,183,434). Eppstein discloses a method of delivering permeant substances through the skin of an animal comprising forming multiple delivery openings in the skin, the majority of the openings having a mean opening depth between 30-50 microns (claim 23, column 5, lines 13-19), wherein 75% of the openings have depth between 50-70 microns, wherein the delivery openings have a range of depths falling within one standard deviation of about 50-90 microns, wherein the openings are formed by a planar array of microneedles by putting a positive pressure force on the microporator by manually pressing down of the microporator, wherein the delivery of substances through the skin results is as effective as a subcutaneous injection, wherein the delivery openings have a distribution that results in bell-shaped curve., and wherein the substances that can be delivered include insulin and hyromorphone. In regards to the claims that recite ranges above 50 microns, the Examiner notes that the term "about" is used to define the ranges. It is the Examiner's position that 50 microns is about 90 microns.

Claims 1-16, 19-36, 39-40, and 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Roser et al. (6,290,991). Roser discloses a method of delivering permeant substances through the skin of an animal comprising forming multiple delivery openings in the skin, the majority of the openings having a mean opening depth between 1-150 microns (column 13, lines 15-20), wherein 75% of the openings have

depth between 50-70 microns, wherein the delivery openings have a range of depths falling within one standard deviation of about 50-90 microns, wherein the openings are formed by a planar array of microneedles by putting a positive pressure force on the microporator by manually pressing down of the microporator, wherein the delivery of substances through the skin results is as effective as a subcutaneous injection, wherein the delivery openings have a distribution that results in bell-shaped curve., and wherein the substances that can be delivered include insulin and hyromorphone.

Claims 1-40, and 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman et al. (6,451,240). Sherman discloses a method of delivering permeant substances through the skin of an animal comprising forming multiple delivery openings in the skin, the majority of the openings having a mean opening depth between 50-250 microns, wherein 75% of the openings have depth between 50-70 microns, wherein the delivery openings have a range of depths falling within one standard deviation of about 50-90 microns, wherein the openings are formed by a planar array of microneedles by putting a positive pressure force on the microporator by manually pressing down of the microporator or can formed by application of a vacuum, wherein the delivery of substances through the skin results is as effective as a subcutaneous injection, wherein the delivery openings have a distribution that results in bell-shaped curve., and wherein the substances that can be delivered include insulin and hyromorphone.

Claims 1-40 and 76-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Eppstein (6,527,716). Eppstein discloses a method of delivering permeant substances through the skin of an animal comprising forming multiple delivery openings

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in the skin, the majority of the openings having a mean opening depth between 1-10,000 microns, wherein 75% of the openings have depth between 50-70 microns, wherein the delivery openings have a range of depths falling within one standard deviation of about 50-90 microns, wherein the openings are formed by a planar array of microneedles by putting a positive pressure force on the microporator by manually pressing down of the microporator or can formed by application of a vacuum, wherein the delivery of substances through the skin results is as effective as a subcutaneous injection, wherein the delivery openings have a distribution that results in bell-shaped curve., and wherein the substances that can be delivered include insulin and hyromorphone.

The applied reference has a common inventor/assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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